

## **FOREWORD: DRUG-DRUG INTERACTION WARNINGS AS TECHNOLOGICAL IATROGENESIS\***

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The Health Information Technology for Economic and Clinical Health Act ("HITECH") contained within the American Recovery and Reinvestment Act of 2009 ("ARRA") provided approximately \$30 billion for Health and Human Services' Agencies: approximately \$27 billion for the Centers for Medicare and Medicaid Services ("CMS") and \$2 billion for the Office of the National Coordinator ("ONC"). The \$27 billion was to fund Medicaid and Medicare incentive payments to non-hospital-based doctors ("eligible providers") and eligible hospitals conditioned on their "meaningful use of certified EMR technology."<sup>1</sup> The incentive payments to providers to adopt electronic medical records ("EMR") are one component in a broader strategy to promote the adoption of health information technology ("HIT") in the United States. In large part this is because research suggests that the benefits of EMR adoption are increased significantly when accompanied by other technologies such as computerized order entry ("CPOE") and clinical decision support ("CDS") modules.<sup>2</sup>

EMR, CPOE and CDS have great potential to reduce the incidence of avoidable adverse events (including medication errors).<sup>3</sup> Yet, these

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1. See generally Nicolas P. Terry, *Certification and Meaningful Use of Electronic Health Records: Reframing Adoption as a Quality and Reimbursement Imperative*, 8 IND. HEALTH L. REV. 45 (2011); Nicolas P. Terry, *Anticipating Stage Two: Assessing the Development of Meaningful Use and EMR Deployment*, 21 ANNALS HEALTH L. 103.

2. See generally David W. Bates et al., *Effect of Computerized Physician Order Entry and a Team Intervention on Prevention of Serious Medication Errors*, 280 JAMA 1311 (1998); Catherine M. DesRoches et al., *Electronic Health Records' Limited Successes Suggest More Targeted Uses*, 29 HEALTH AFF. 639 (2010).

3. Cf. Daria O'Reilly et al., *Cost-Effectiveness of a Shared Computerized Decision Support System for Diabetes Linked to Electronic Medical Records*, J. AM. MED. INFORMATICS ASS'N (Nov. 3, 2011), <http://jamia.bmj.com/content/early/2011/11/03/amiajnl-2011-000371.full.pdf> (showing only marginal improvement in trial involving treatment of diabetes type 2).

technologies themselves possess error profiles and so the potential to add to iatrogenic injuries.<sup>4</sup> As noted by Harrington and colleagues:

While hospital electronic medical records (EMR) are intended to reduce medical errors, several aspects of the EMR may actually increase the incidence of certain types of errors or produce new safety risks that result in harm. Threats to patient safety can be introduced during any phase of the EMR lifecycle, such as planning, design, development, testing, implementation, operations, and maintenance. Within each of these processes, technology, people, and the work environment can individually or collectively generate errors.<sup>5</sup>

In a timely study that likely will exert considerable influence on the design of future HIT safety models M. Susan Ridgely and Michael Greenberg critically examine Drug-Drug Interaction ("DDI") alerts initiated by CDS systems. Specifically, they explore two related phenomena; first, the tendency of CDS to generate a very large number of DDI alerts that leads to high sorting costs for physicians (they appropriately term this "alert fatigue") and, second, the liability disincentives that create barriers to some possible solutions to this alert fatigue. Such solutions could include more physician choice in electing to receive fewer or filtered alerts (arguably increasing physician exposure to malpractice liability) or a reduced DDI model in the CDS (arguably increasing manufacturer exposure to products liability). As the authors note, "What is needed is an optimized DDI list, but vendors are unlikely to produce one, given their concern that excluding any potential drug interactions from the list (or allowing their clients to do so) exposes the vendor to additional liability risk."<sup>6</sup> There is the additional danger that CDS manufacturers will tend towards the production of "defensive" software featuring over-inclusive DDI lists.

In the absence of any discovered "legal 'magic bullet'" the authors analyze the amelioratory potential of five strategies to address liability concerns.<sup>7</sup> First, a national "expert" process that would then create a norm in medical malpractice claims (although it would be of less utility in products

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4. Patrick A. Palmieri et al., *Technological Iatrogenesis: New Risks Force Heightened Management Awareness*, J. HEALTHCARE RISK MGMT., Autumn (Fall) 2007, at 19.

5. Linda Harrington et al., *Safety Issues Related to the Electronic Medical Record (EMR): Synthesis of the Literature from the Last Decade, 2000-2009*, 56 J. HEALTHCARE MGMT. 31 (2011); see generally Nicolas P. Terry, *When the "Machine That Goes 'Ping'" Causes Harm: Default Torts Rules and Technologically-Mediated Health Care Injuries*, 46 St. Louis U. L.J. 37 (2002).

6. M. Susan Ridgely & Michael D. Greenberg, *Too Many Alerts, Too Much Liability: Sorting Through the Malpractice Implications of Drug-Drug Interaction Clinical Decision Support*, 5 ST. LOUIS U. J. HEALTH L. & POL'Y 257, 259 (2012).

7. *Id.* at 263.

liability cases where custom-based evidence is viewed less favorably).<sup>8</sup> Second, FDA regulation coupled with preemption.<sup>9</sup> Third, incorporating an optimized DDI list in meaningful use (presumably stage 3).<sup>10</sup> Fourth, including an optimized DDI list in ONC's meaningful use certification requirements.<sup>11</sup> Fifth, introducing federal legislation that contains a safe harbor for those who adopt an approved DDI list.<sup>12</sup>

Ridgely and Greenberg identify an intrinsically important issue: the practical and legal implications of a non-optimized DDI list. But, that issue serves also as a broader metaphor. Anyone who has seen a physician wrestle with a newly introduced EMR terminal in his or her office will appreciate the flaws in the early generations of HIT appliances. Over-inclusive data presentation models, relatively unsophisticated interface design, and steep learning curves experienced by health care professionals are colliding with accelerating adoption curves promoted by HHS and embraced by healthcare entities eager to share in the meaningful use bounty.

The importance of the issue can further be gauged from the quality of the commentaries that follow. Sharona Hoffman and Andy Podgurski,<sup>13</sup> two of the leading academic commentators on the safety of HIT products, address the operational pieces missing from Ridgely and Greenberg's article—exactly what is meant by a clinically significant DDI list and what would be the process to achieve such a list. Their conclusion is that context or patient specific parsing of DDI information (informed by expert-designed algorithms and patient-specific EHR data) is preferable to notional or canonical lists.

In his commentary Dr. Ross Koppel<sup>14</sup> points out that CDS issues go beyond the DDI problems identified by Ridgely and Greenberg, extending to many more data sets, that the amount of data and the lack of clear evidence-based discriminators between CDS alerts make for a frustrating user experience, and a lack of consistency among products and implementing facilities. His plea is for better CDS systems as well as improved liability options.

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8. *Id.* at 279.

9. *Id.* at 281.

10. *Id.* at 286.

11. Ridgely & Greenberg, *supra* note 6, at 289.

12. *Id.* at 290.

13. Sharona Hoffman & Andy Podgurski, *Drug-Drug Interaction Alerts: Emphasizing the Evidence*, 5 ST. LOUIS U. J. HEALTH L. & POL'Y 297 (2012).

14. Ross Koppel, *The Marginal Utility of Marginal Guidance: Commentary on Too Many Alerts, Too Much Liability: Sorting Through the Malpractice Implications of Drug-Drug Interaction Clinical Decision Support* by M. Susan Ridgely and Michael D. Greenberg, 5 ST. LOUIS U. J. HEALTH L. & POL'Y 311 (2012).

Dr. David Bates<sup>15</sup> stresses the major safety benefits of CDS systems, detailing their positive worth even compared to EMR. He expresses his core agreement with Ridgely and Greenberg as “clinical decision support is especially tricky, since not having enough is a problem, but so is having too many false positive warnings.”<sup>16</sup> While generally approving of Ridgely and Greenberg’s five strategies, Bates emphasizes that “the vast bulk of DDIs including most of the ones with clinical consequences occur in the range that is in the middle of these two [clinically significant and insignificant] areas.”<sup>17</sup>

Finally, Jodi Daniel<sup>18</sup> from ONC provides the important policymaker’s perspective and, specifically, the appropriateness of regulation. In Daniel’s view “in the case of DDI alerts and liability, the market has not developed a solution for the liability risk. This failure impedes quality and safety improvements in health care.”<sup>19</sup> However, she is cool to all out FDA regulation preferring a more targeted approach to improving CDS interfaces to reduce alert fatigue.

Ridgely and Greenberg, together with their commentators identify an important issue and lay much of the groundwork for what is likely to be a fascinating policy tussle. As is well known, the FDA has been monitoring iatrogenic HIT events and has characterized its own regulatory inaction as an exercise of discretion as it evaluates the field.<sup>20</sup> Notwithstanding, there is some evidence that the FDA has developed a roadmap for HIT regulation.<sup>21</sup> To assuage ONC and CMS concerns that FDA regulation would slow the meaningful use rollout the Institute of Medicine (“IOM”) was asked to weigh in on the issue. In its November 2011 report, *Health IT and Patient Safety: Building Safer Systems for Better Care*, the IOM appears to have sided with ONC and CMS. It recommends that a new entity, the Health IT Safety Council, should be established within HHS to collect and provide

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15. David W. Bates, *Clinical Decision Support and the Law: The Big Picture*, 5 ST. LOUIS U. J. HEALTH L. & POL’Y 319 (2012).

16. *Id.* at 320.

17. *Id.* at 322.

18. Jodi G. Daniel, *Addressing Liability and Clinical Decision Support: A Federal Government Role*, 5 ST. LOUIS U. J. HEALTH L. & POL’Y 325 (2012).

19. *Id.* at 328.

20. *Health Information Technology (HIT) Policy Committee Adoption/Certification Workgroup* (testimony by Jeffrey Shuren, Dir. of FDA Ctr. for Devices and Radiological Health) (Feb. 25, 2010), available at [http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS\\_0\\_10741\\_910717\\_0\\_0\\_18/3Shuren\\_Testimony022510.pdf](http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10741_910717_0_0_18/3Shuren_Testimony022510.pdf).

21. See Medical Devices; Medical Device Data Systems, 76 Fed. Reg. 8637 (Feb. 15, 2011); U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF: MOBILE MEDICAL APPLICATIONS (2011), available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf>.

information and set safety standards.<sup>22</sup> Reacting to the report ONC Coordinator Dr. Farzad Mostashari noted, "HHS agrees with IOM that more can and should be done to capture safety issues unique to EHRs when and if they arise. ONC will lead an HHS planning initiative to develop a comprehensive EHR safety action and surveillance plan well within the 12-month period recommended by IOM."<sup>23</sup> That statement fails to mention that the proposed Safety Council suggests a preference for post-marketing surveillance absorption into meaningful use certification. Meanwhile, and reinforcing Ridgely and Greenberg's investigation of several liability-limiting options, Rep. Tom Marino has introduced legislation that would have the effect of denying FDA regulation of EMR while at the same time providing that reports of EHR-related adverse events will not be admissible in any litigation.<sup>24</sup>

There will be many more issues related to HIT outputs that will have liability dimensions as the healthcare industry undergoes this overdue revolution. These are all excellent contributions to the literature and on behalf of the editors of the *Saint Louis University Journal of Health Law & Policy*, I express our thanks to the participating authors.

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22. COMM. ON PATIENT SAFETY & HEALTH INFO. TECH., INST. OF MED., HEALTH IT AND PATIENT SAFETY: BUILDING SAFER SYSTEMS FOR BETTER CARE (2011), available at [http://www.nap.edu/openbook.php?record\\_id=13269&page=13](http://www.nap.edu/openbook.php?record_id=13269&page=13).

23. Farzad Mostashari, *Improving Patient Safety through Health IT*, HEALTHITBUZZ (Nov. 8, 2011, 5:53 PM), <http://www.healthit.gov/buzz-blog/electronic-health-and-medical-records/patient-safety-healthit/>.

24. Safeguarding Access For Every Medicare Patient Act, H.R. 3239, 112th Cong. (2011).



# SYMPOSIUM ARTICLES

